

Patent Application No. 09/469,399

IN THE SPECIFICATION:

Please replace the phrase "one or two" located at page 6, line 28, with the phrase "two or three."

Please insert the word "BRIEF" before the word "DESCRIPTION" at page 10, line 3.

IN THE CLAIMS:

Please amend claims 1 and 15 as set forth below. Applicants note that all claims currently pending in the application are shown below for clarity.

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Claim 1 (Currently Amended): An active agent dosage form comprising:
a first layer comprising an amount of swellable polymer, said amount being sufficient to swell said first layer such that the active agent dosage form is retained within a stomach of a subject;
a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to swell to a lesser extent than the first layer; and
at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer.

Claim 2 (Previously Amended): The active agent dosage form of claim 1, wherein the number average molecular weight of the swellable polymer is between about 100,000 and 20,000,000 grams per mole.

Claim 3 (Previously Amended): The active agent dosage form of claim 2, wherein the swellable polymer is polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch, guar gum, sodium alginate, or polyvinyl alcohol.

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Claim 4 (Previously Amended): The active agent dosage form of claim 1, wherein the second layer comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, a cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars, and sodium chloride, and the first layer optionally comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars and sodium chloride.

Claim 5 (Previously Amended): The active agent dosage form of claim 1, wherein the first layer swells more rapidly than does the second layer.

Claim 6 (Previously Amended): The active agent dosage form of claim 1, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

Claim 7 (Previously Amended): The active agent dosage form of claim 1, wherein the second layer includes 5 to 99.99 weight percent of a swellable polymer and further includes up to 60 weight percent, inclusive, of a hydroattractant.

Claim 8 (Previously Amended): The active agent dosage form of claim 1, wherein the first layer is formulated such that the active agent dosage form is retained within the stomach for a prolonged period of time.

Claim 9 (Previously Amended): The active agent dosage form of claim 1, wherein the first layer is formulated such that the active agent dosage form is retained within the stomach for between about 6 to 12 hours.

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Claim 10 (Previously Amended): The active agent dosage form of claim 1, wherein the first layer comprises polyethylene oxide having a number average molecular weight of at least 100,000 grams per mole.

Claim 11 (Previously Amended): The active agent dosage form of claim 10, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

Claim 12 (Previously Amended): The active agent dosage form of claim 11, wherein the active agent is acyclovir, ganciclovir, ritonavir, minocycline, cimetidine, ranitidine, captopril, methyldopa, selegiline, minocycline, fexofenadine, metformin, bupropion, orlistat or a pharmaceutically acceptable salt thereof.

Claim 13 (Previously Amended): The active agent dosage form of claim 10, wherein the active agent is metformin or a pharmaceutically acceptable salt thereof.

Claim 14 (Previously Amended): The active agent dosage form of claim 1, wherein the second layer comprises an active agent selected from the group consisting of acyclovir, ganciclovir, ritonavir, metformin, bupropion, orlistat and minocycline, and the second layer comprises a bioerodible polymer, wherein the dosage form is formulated to release a therapeutically-effective amount of the active agent to the stomach of a subject over at least a 3 hour period.

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Claim 15 (Currently Amended): A method for treating a subject in need thereof with an active agent, the method comprising:

administering to the subject a multilayered dosage form which is retained in a stomach of the subject over a prolonged period of time, the dosage form comprising:

C2 a first layer comprising an amount of swellable polymer, said amount being sufficient to swell said first layer such that said active agent dosage form is retained within the stomach of a subject;

a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to swell to a lesser extent than the first layer; and

at least one band of insoluble material circumscribing only a portion of said first layer and said second layer, said at least one band of insoluble material binding together the first layer and the second layer.

Claim 16 (Previously Amended): The method of claim 15, which comprises administering one or more of the multilayered dosage forms to the subject in the fed state at the start of each dosing period.

Claim 17 (Previously Amended): The method of claim 16, wherein the administration of one or more of the multi-layered dosage forms occurs within one hour of the subject consuming food.

Claim 18 (Previously Amended): The active agent dosage form of claim 1, further comprising a gastric-emptying delaying agent.

Claim 19 (Previously Amended): The active agent dosage form of claim 18, wherein the gastric-emptying delaying agent is selected from anticholinergic agents, methylcellulose, guar gum, fats and fatty acids of 10-15 carbon atoms.

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Claim 20 (Previously Amended): The active agent dosage form of claim 1, wherein the active agent comprises a liquid active agent formulation.

Claim 21 (Previously Amended): The active agent dosage form of claim 20, wherein the liquid active agent formulation is sorbed into porous particles.

Claim 22 (Previously Amended): The active agent dosage form of claim 21, wherein the porous particles are calcium hydrogen phosphate or magnesium aluminometasilicate.

Claim 23 (Previously Amended): The active agent dosage form of claim 1, wherein the dosage form comprises a pH regulating agent.

Claim 24 (Previously Amended): The active agent dosage form of claim 21, wherein the liquid active agent formulation comprises a pH regulating agent selected from organic and inorganic acids and bases.

Claim 25 (Previously Amended): The active agent dosage form of claim 21, wherein the liquid active agent formulation comprises a chelating agent.

Claim 26: The active agent dosage form of claim 8, wherein the prolonged period of time is at least 3 hours.